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PATENT COOPERATION TREATY



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-278 WO		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IB 03/03092	International filing date (day/month/year) 01.08.2003	Priority date (day/month/year) 02.08.2002	
International Patent Classification (IPC) or both national classification and IPC A61K31/545			
Applicant RANBAXY LABORATORIES LIMITED et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 02.03.2004		Date of completion of this report 26.11.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Vermeulen, S Telephone No. +49 89 2399-7520 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/B 03/03092**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-10 as originally filed

Claims, Numbers

1-53 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 53

because:

☒ the said international application, or the said claims Nos. 53 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-53
Inventive step (IS)	Yes: Claims	
	No: Claims	1-53
Industrial applicability (IA)	Yes: Claims	1-52
	No: Claims	53 (no opinion)

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 53 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: CHAKRABARTI P K ET AL: 'Dispersible tablet dosage forms - [beta]-Lactum antibiotics' INDIAN JOURNAL OF PHARMACEUTICAL SCIENCES 1992 INDIA, vol. 54, no. 3, 1992, pages 107-109, XP009027833 ISSN: 0250-474X
- D2: EP-A-0 281 200 (GIST BROCADES NV) 7 September 1988
- D3: FR-A-2 814 679 (CLL PHARMA) 5 April 2002
- D4: WO 99 18965 A (KOUTRIK ROBERTUS CORNELIS VAN ;YAMANOUCHI EUROP BV (NL)) 22 April 1999
- D5: EP-A-0 627 218 (NIPPON SHINYAKU CO LTD) 7 December 1994

1. The subject-matter of independent claims 1, 28 and 53 is not considered novel (Art. 33(2) PCT) in view of prior art disclosures which can be taken from D1-D5. Said prior art documents disclose processes and/or compositions which fall within the definition of the above mentioned claims.
 - 1.1 A dispersible tablet comprising cephalexin and suitable excipients is disclosed in D1 (cf. page 108, table 1). The tablet is made according to the wet granulation technique and the disclosed excipients include several disintegrants, binders, fillers, lubricating agents and flavouring agents.
 - 1.2 Similarly the prior art documents D2, D3 and D5 disclose dispersible tablets

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comprising cephalexin in combination with disintegrants and other excipients (cf. passages cited in the ISR). Furthermore, said documents also disclose wet granulation as suitable process of manufacture of the dispersible cephalexin tablets.

2. The dependent claims do not appear to contain any additional features which, in combination with the features of any claim to which they refer, would render the claimed subject-matter novel and/or inventive (Art.33(2)-(3) PCT). The specific embodiments are generally known and suggested by the cited prior art documents. Furthermore, the additional features do not appear to provide a solution to any specific problem, as compared to the state of the art, which solution would involve an inventive step.